UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,416	12/10/2001	Cynthia C. Bamdad	067456-5020US01	1226

67374 7590 09/27/2007

MORGAN, LEWIS & BOCKIUS, LLP
ONE MARKET SPEAR STREET TOWER
SAN FRANCISCO, CA 94105

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	
MAIL DATE	**DELIVERY MODE**
09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/016,416	BAMDAD ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18 and 20-27* is/are pending in the application.

4a) Of the above claim(s) *26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,20-25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on July 27, 2007 have been entered. The claims pending in this application are claims 18 and 20-27 wherein claim 26 has been withdrawn due to species election. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on July 27, 2007 Therefore, claims 18, 20-25, and 27 will be examined.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 18, 20, 24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, (US Patent No.6,319,670 B1, filed on December 23, 1997) in view of Meade *et al.*, (US Patent No. 5,770,369, filed on June 7, 1996) and Roberts *et al.*, (US Patent No. 5,958,791, filed on September 27, 1996).

Sigal *et al.*, teach that method and apparatus for improved luminescence assays using microparticles.

Regarding claims 18, 24, and 27, Sigal *et al.*, teach a composition comprising (i) a sample, (ii) microparticles (ie., colloidal gold particles) comprised of an electrically conductive material having one or more copies of a first assay-ligand immobilized on its surface and a plurality of ECL moieties immobilized on its surface and (iii) a second assay-ligand immobilized on an electrode wherein said first and second assay-ligands are different in structure and/or specificity (see column 4, last paragraph and column 12, second paragraph) and the ECL moieties include transition metal complexes (see column 9, first paragraph), and claim 18 does not require that a first binding ligand has an ability to interact with a second binding ligand, Sigal *et al.*, disclose an electrode comprising a first binding ligand (ie., said second assay-ligand) and a plurality of colloids each comprising: i) a second binding ligand (ie., said first assay-ligand); and ii) an electron transfer moiety such as a transition metal complex as recited in a) and b) of claim 18 and claim 24. Since Sigal *et al.*, teach that a first assay-ligand and a second assay-ligand are nucleic acids (see column 3, fourth paragraph), Sigal *et al.*, disclose that said first binding ligand is a first nucleic acid and said second binding ligand is a second nucleic acid as recited in claim 27.

Regarding claim 20, Sigal *et al.*, teach that said plurality of colloids comprise a self-assembled monolayer as recited in claim 20 (see column 8, second paragraph).

Sigal *et al.*, do not disclose a substrate comprising an array of electrodes and a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety as recited in a) and c) of claim 18. However, Sigal *et al.*, teach electrochemical cells

having electrodes for ECL measurement by detecting light emitted from the working electrode surface based on the integrated photocurrent (see column 9, first paragraph and column 17, left column), Sigal *et al.*, disclose a detector capable of detecting said electron transfer moiety (ie., ECL comprising transition metal complex) as recited in c) of claim 18.

Meade *et al.*, teach that a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety (see column 27, left column).

Roberts *et al.*, teach advantages of fabricating small electrodes in interdigitated arrays (see column 7, last paragraph bridging to column 8, second paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition recited in claim 18 comprising a substrate comprising an array of electrodes (ie., a plurality of identical electrodes, each has a second assay-ligand) and a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety in view of the patents of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*. One having ordinary skill in the art would have been motivated to do so because Roberts *et al.*, suggest that advantages of fabricating small electrodes in interdigitated arrays "[M]icroelectrodes fabricated in an interdigitated array have inherent advantages in signal detection over more conventional electrode configurations... Scaling down the size of an individual electrode has the advantage of increasing the rate of mass transport, increasing the signal-to-noise (faradaic/charging current) ratio, and decreasing ohmic signal losses... Advantages of fabricating small electrodes in interdigitated arrays go even further by allowing redox cycling of ions back and forth between anode(s) and cathode(s)... This generates much larger currents for detection and allows for the use of extremely small sample volumes" (see

column 8) and the simple replacement of one kind of detector (ie., the detector capable of detecting the integrated photocurrent associated with electron transfer from said ECL comprising electron transfer moiety taught by Sigal *et al.*,) from another kind of detector (ie., the detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety taught by Meade *et al.*,) during the process of making a composition recited in claim 18 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the methods capable of detecting an electron transfer moiety are exchangeable (see Meade *et al.*, column 25, fifth paragraph) and the detector capable of detecting the integrated photocurrent associated with electron transfer from said ECL comprising electron transfer moiety taught by Sigal *et al.*, and the detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety taught by Meade *et al.*, are used for the same purpose (ie., detecting electron transfer of the transition metal complex).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In page 4, fourth paragraph bridging to page 6, third paragraph of applicant's remarks, applicant argues that: (1) "a critical step in electrochemiluminescence assays is the detection of photons. Claim 18 recites a detector capable of detecting a voltage associated with electron transfer from an electron transfer moiety. Such detector does not detect photons, and so would change the principle of operation of the composition taught by Sigal"; (2) "[T]he compositions and methods for conducting electrochemiluminescence binding assays of Sigal would not achieve their intended purpose if the detector of claim 18 replaced the photomultiplier tube in Sigal. Since the detector of claim 18 does not detect photons, ligand binding according to Sigal could not be detected".; (3) "[T]he Examiner suggests on page 4 of the Office Action that replacement of an optical detector with an electrical detector would have been obvious because 'the methods capable of detecting an electron transfer moiety are exchangeable (see Meade *et al.*, column 25, fifth paragraph).' However, the Examiner has mischaracterized the teaching of Meade. In column 25, lines 42-47, Meade teaches that '**Electron transfer** through nucleic acid can be detected in a variety of ways. A variety of detection methods may be used including, but not limited to, optical detection.., and electronic detection[.]'(emphasis added) According to Meade, depending on the choice of electron transfer moieties, electron transfer is detected in some cases optically and in some cases by detecting voltages. The fact that either optical or electronic detection can be used to detect electron transfer does not mean that one of skill in the art would use the detector of claim 18 to replace the photomultiplier tube of Sigal, where emitted photons, not electron transfer, are being directly detected. In other words, the existence of at least two devices to detect **electron transfer** as taught by Meade does not lead to the conclusion that

those two devices are interchangeable for detecting photons in the manner taught by Sigal. A voltage detector does not detect photons. The Examiner, who must state a reason to combine the references even under KSR in order to establish a prima facie case of obviousness, has proffered no reason as to why one of skill in the art would use the detector of claim 18 for detecting a voltage associated with electron transfer from an electron transfer moiety in an assay where the principle of operation is the detection of **photons**. The Examiner has thus failed to establish a prima facie case of obviousness. Even assuming for the sake of argument that the Examiner has met his burden, Applicants have rebutted any prima facie case of obviousness by showing that modification of the primary reference would change the principle of its operation and further render it unsatisfactory for its intended purpose"; and (4) "[A]pplicants note that claim 18 recites 'an array of working electrodes.' The interdigitated arrays in Roberts, column 7, line 66 to column 8, line 26, as cited by the Examiner, are not working electrodes. Roberts states that '[a]dvantages of fabricating small electrodes in interdigitated array go even further by allowing redox cycling of ions back and forth between anode(s) and cathode(s).'This passage implies that the interdigitated array of, Roberts comprises not working electrodes, but rather, one working electrode having multiple fingers interdigitated with one reference electrode also having multiple fingers. Furthermore, the advantages of increasing the size of mass transport, increasing the signal-to-noise (faradaic/charging current) ratio, and decreasing ohmic signal losses" are in reference to the small scale of the electrodes, rather than to any configuration of working arrays".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, since Sigal *et al.,* teach electrochemical cells having electrodes for ECL measurement by detecting light emitted from the working electrode surface based on the

integrated photocurrent (see column 9, first paragraph and column 17, left column) and it is known that ECL process includes electron transfer (see attached ELC Diagram) and ECL is used as the basis of the electron transfer detection (see Meade *et al.*, column 26, lines 62-67), Sigal *et al.*, disclose a detector capable of detecting said electron transfer moiety (ie., ECL comprising transition metal complex) by measuring the integrated photocurrent. Since Meade *et al.*, teach a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety (see column 27, left column), the detector capable of detecting the integrated photocurrent associated with electron transfer from said ECL comprising electron transfer moiety taught by Sigal *et al.*, and the detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety taught by Meade *et al.*, are used for the same purpose (ie., detecting electron transfer of the transition metal complex) and the replacement of the detector capable of detecting the integrated photocurrent associated with electron transfer from said ECL comprising electron transfer moiety taught by Sigal *et al.*, from the detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety taught by Meade *et al.*, during the process of making a composition recited in claim 18 would not change the principle of operation of the composition and the intended use of Sigal *et al.*. Furthermore, Meade *et al.*, suggest that the methods capable of detecting an electron transfer moiety are exchangeable (see column 25, fifth paragraph). Second, since Sigal *et al.*, teach electrochemical cells having electrodes for ECL measurement by detecting light emitted from the working electrode surface based on the integrated photocurrent (see column 9, first paragraph and column 17, left column) and it is known that ECL process includes electron transfer (see attached ELC Diagram), and ECL is used as the basis of the electron transfer detection (see

Meade *et al.*, column 26, lines 62-67), the detector taught by Sigal *et al.*, is capable of detecting electron transfer and the examiner has not mischaracterized the teaching of Meade *et al.*, as argued by applicant. Third, although the examiner agrees with applicant that "[A] voltage detector does not detect photons", as shown above, the detector capable of detecting the integrated photocurrent associated with electron transfer from said ECL comprising electron transfer moiety taught by Sigal *et al.*, and the detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety taught by Meade *et al.*, are used for the same purpose (ie., detecting electron transfer of the transition metal complex), the detector taught by Sigal *et al.*, and the detector taught by Meade *et al.*, are exchangeable in order to detect electron transfer of the transition metal complex. Fourth, although Roberts *et al.*, does not disclose an array of working electrodes as recited in claim 18, Roberts *et al.*, suggest that advantages of fabricating small electrodes in interdigitated arrays "[M]icroelectrodes fabricated in an interdigitated array have inherent advantages in signal detection over more conventional electrode configurations... Scaling down the size of an individual electrode has the advantage of increasing the rate of mass transport, increasing the signal-to-noise (faradaic/charging current) ratio, and decreasing ohmic signal losses... Advantages of fabricating small electrodes in interdigitated arrays go even further by allowing redox cycling of ions back and forth between anode(s) and cathode(s)... This generates much larger currents for detection and allows for the use of extremely small sample volumes" (see column 8). Furthermore, since Sigal *et al.*, teach working electrodes as recited in claim 18 and Meade *et al.*, teach that a detector capable of detecting the voltage associated with electron transfer from said electron transfer moiety (see column 27, left column), it would have been obvious to one having ordinary skill in the art at the

time the invention was made to have made a composition recited in claim 18 in view of the patents of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*. Note that the rejection on 18, 20, 24, and 27 is based on the combination of the patents from Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, and is not dependent on whether Roberts *et al.*, teach working electrodes or not as argued by applicant.

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above, and further in view of Bamdad *et al.*, (US Patent No. 5,620,850, published on April 15, 1997).

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, do not disclose that said self-assembling monolayer comprises an alkyl chain as recited in claim 21. However, Sigal *et al.*, teach that a self-assembling monolayer is made by functionalized thiol or silane (see column 8, second paragraph).

Bamdad *et al.*, teach that a self-assembling monolayer is made by alkyl thiol functional groups (see columns 9 and 10).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 21 wherein said self-assembling monolayer comprises an alkyl chain in view of the patents of Sigal *et al.*, Meade *et al.*, Roberts *et al.*, and Bamdad *et al.*. One having ordinary skill in the art would have been motivated to do so because Sigal *et al.*, suggest that functionalized thiol is used to

make a self-assembling monolayer (see column 8, second paragraph) and Bamdad *et al.*, have successfully made a self-assembling monolayer using one kind of functionalized thiol, alkyl thiol functional groups (see columns 9 and 10). One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to make a self-assembling monolayer using one kind of functionalized thiol, alkyl thiol functional groups.

Response to Arguments

In page 6, first paragraph bridging to page 7, first paragraph of applicant's remarks, applicant argues that "[A]s argued above, claim 18 is not obvious over Sigal in view of Meade and Roberts, Bamdad, directed toward derivatized surfaces for surface plasmon resonance experiments, does not cure the deficiencies of the references. Therefore, not all of the limitations of claim 21 are found in the cited references, and so a prima facie case of obviousness has not been established for claim 21".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because the combination of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, do teach all limitations recited in claim 18 (see above Response to Arguments) and the patent from Bamdad *et al.*, is not used to cure the deficiencies of the references as argued by applicant.

5. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above, and further in view of Gerpheide *et al.*, (US Patent No. 5,565,658, published on October 15, 1996).

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, do not disclose that said substrate is a printed circuit board as recited in claim 22.

Gerpheide *et al.*, teach that the substrate of an electrode array is a printed circuit board (see Figure 3b).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 22 wherein said substrate is a printed circuit board in view of the patents of Sigal *et al.*, Meade *et al.*, Roberts *et al.*, and Gerpheide *et al.*. One having ordinary skill in the art would have been motivated to do so because Gerpheide *et al.*, have successfully used a printed circuit board as a substrate to make an array of electrodes and fabrication of electrodes on a printed circuit board would provide an economical and widely available way to make an array of electrodes (see Gerpheide *et al.*, column 5, lines 39-48). One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to use a printed circuit board as a substrate to make an array of electrodes.

Response to Arguments

In page 7, first paragraph bridging to page 7, first paragraph of applicant's remarks, applicant argues that "[A]ssuming for the sake of argument that Roberts teaches an array of working electrodes, Roberts teaches at column 5, lines 32-34, that its device 'includes an absorbent material, having a contact portion proximate to one end for contact with and uptake of the test solution.' Each of the conductors in Roberts 'comprises a plurality of fingers disposed on the absorbent material.' Id. at lines 37-38" and "[G]erpheide, however, teaches at column 5, lines 28-30, that 'the electrode array may utilize a flexible printed circuit board, such as a flex circuit,

or stampings of sheet metal or metal foil.' One of skill in the art would understand that sheet metal and metal foil are not absorbent materials. Furthermore, one of skill in the art would understand that substrates used in flex circuits are preferably not absorptive. See Joseph Fjelstad, *Flexible circuit Technology* 43 (3d ed. 2007) (attached as Exhibit A; "Moisture absorption is definitely not desirable for any flexible substrate. Moisture can negatively impact both the manufacturing process (by causing delamination, in process or in assembly) and the performance of the finished product (by altering the material's dielectric constant and increasing signal loss.)") Thus, one of skill in the art would not be motivated to modify, Roberts in view of Gerpheide to arrive at the presently claimed invention because the nonabsorptive printed circuit boards of Gerpheide would render the electrodes of Roberts unsatisfactory for their intended purpose, Indeed, Gerpheide explicitly teaches away from Roberts and so one of skill in the art would not be motivated to modify Roberts in view of Gerpheide".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Although the examiner agrees with applicant that "sheet metal and metal foil are not absorbent materials", the rejection is not based on the replacement of absorbent materials from sheet metal and metal foil as argued by applicant. Regarding the rejection of claim 18, Roberts *et al.,* teach advantages of fabricating small electrodes in interdigitated arrays (see column 7, last paragraph bridging to column 8, second paragraph), the examiner does not indicate that the array recited in claim 18 must comprise absorbent materials in the device of Roberts *et al.*.

6. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above, and further in view of Kayyem *et al.*, (US Patent No. 6,096,273, filed on November 5, 1996).

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, do not disclose that said electrodes are gold as recited in claim 23.

Kayyem *et al.*, teach to covalently attach nucleic acids (ie., binding ligands as recited in claim 18) to an electrode such as a gold electrode (see column 4 and Figure 4). The different materials such as gold, silicon, carbon and metal oxide are used to make electrodes and these electrodes are exchangeable (see column 20, lines 40-65).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 23 wherein said electrodes are gold in view of the patents of Sigal *et al.*, Meade *et al.*, Roberts *et al.*, and Kayyem *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple replacement of one kind of electrode (ie., electrodes taught by Sigal *et al.*,) from another kind of electrode (ie., gold electrodes taught by Kayyem *et al.*,) during the process of making a composition recited in claim 23 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since Kayyem *et al.*, suggest that electrodes are exchangeable (see column 20, lines 40-65),

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above, and further in view of Kayyem *et al.*, (November 5, 1996).

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, do not disclose that said transition metal complex is ferrocene as recited in claim 25.

Kayyem *et al.*, teach that electron transfer moieties are different transition metal complexes such as ferrocene. These different transition metal complexes are exchangeable (see column 29, lines 31-42).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition recited in claim 25 wherein said transition metal complex is ferrocene in view of the patents of Sigal *et al.*, Meade *et al.*, Roberts *et al.*, and Kayyem *et al.*. One having ordinary skill in the art would have been motivated to do

so because Kayyem *et al.,* have successfully used ferrocene as an electron transfer moiety and the simple replacement of one kind of transition metal complex (ie., a transition metal complex taught by Sigal *et al.,*) from another kind of transition metal complex (ie., a transition metal complex such as ferrocene taught by Kayyem *et al.,*) as an electrode transfer moiety during the process of making a composition recited in claim 25 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since Kayyem *et al.,* suggest that electron transfer moieties for attaching to a nucleic acid are exchangeable (see column 29, lines 31-42),

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In page 8, third paragraph bridging to page 9, second paragraph of applicant's remarks, applicant argues that "[T]he present application 10/016,416 and US Patent 6,096,273 were, at the time the invention of 10/016,416 was made, owned by Clinical Micro Sensors, Inc. Assignment of US Patent 6,096,273 to Clinical Micro Sensors, Inc., can be bound at reel/frame 008406/0741, recorded March 17, 1997. Assignment of the present application to Clinical Micro Sensors, Inc., can be bound at reel/frame 010625/0568, recorded March 20, 2000. In view of the above

statement of common ownership as well as the referenced assignments, US Patent 6,096,273 is not available as a basis of rejection of claims 23 and 25 under 35 USC 103(a)".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because the examiner cannot locate the assignment for this instant application.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above.

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, and Roberts *et al.*, do not disclose that said electrodes are gold as recited in claim 23. However, Meade *et al.*, teach that an electrode is made of conductive material such as gold, vitreous carbon, graphite, and other conductive materials and these electrodes are exchangeable (see column 9, lines 27-39).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition as recited in claim 23 wherein said electrodes are gold in view of the patents of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple replacement of one kind of electrode (ie., electrodes taught by Sigal *et al.*,) from another kind of electrode (ie., gold electrodes taught by Meade *et al.*,) during the process of making a composition recited in claim 23 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was

made since Meade *et al.*, suggest that different electrodes are exchangeable (see column 9, lines 27-39).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal *et al.*, in view of Meade *et al.*, and Roberts *et al.*, as applied to claims 18, 20, 24, and 27 above.

The teachings of Sigal *et al.*, Meade *et al.*, and Roberts *et al.*, have been summarized previously, *supra.*

Sigal *et al.*, and Roberts *et al.*, do not disclose that said transition metal complex is ferrocene as recited in claim 25.

Meade *et al.*, teach that electron transfer moieties are different transition metal complexes such as ferrocene. These different transition metal complexes are exchangeable (see column 25, lines 7-20).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a composition recited in claim 25 wherein said transition metal complex is ferrocene in view of the patents of Sigal *et al.*, Meade *et al.*, and

Roberts *et al.*. One having ordinary skill in the art would have been motivated to do so because Meade *et al.*, have successfully used ferrocene as an electron transfer moiety and the simple replacement of one kind of transition metal complex (ie., a transition metal complex taught by Sigal *et al.*,) from another kind of transition metal complex (ie., a transition metal complex such as ferrocene taught by Meade *et al.*,) as an electrode transfer moiety during the process of making a composition recited in claim 25 would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since Meade *et al.*, suggest that electron transfer moieties for attaching to a nucleic acid are exchangeable (see column 25, lines 7-20).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07, and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

September 20, 2007

FRANK LU
PRIMARY EXAMINER